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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/030,132 | 01/25/2002 | Hiroaki Nishiuchi | 218070US0PCT | 8138 |
| 22850 | 7590 | 10/28/2003 | | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER MARX, IRENE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/030,132 | NISHIUCHI ET AL. | |
| | Examiner | Art Unit | |
| | Irene Marx | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed 8/19/03 is acknowledged. Claims 1-9 are under examination. Applicant's election with traverse of claims 1-5 and 7-9 is being considered on the merits.

The traversal is on the ground(s) that because the Office has not demonstrated that a traditional method of fermentation would produce a strain as claimed and because the reference provided does not support the conclusion of having the required amounts of glutathione and γ -glutamylcysteine, the restriction is improper.

First, Applicant fails to consider that the claim as written merely requires a strain that **"can contain"** a certain amount of γ -glutamylcysteine. The cited reference discloses a yeast containing 2-20% of glutathione and/or γ -glutamylcysteine (See, e.g., Abstract). Second, the claim limitations are further conditional regarding the stipulation that the amount "can" be in the strain "when" the strain is cultured under certain circumstances. Third, the method of claim 6 requires production of a recombinant strain be produced. This limitation is not found in Claim 1. Therefore the yeast disclosed is substantially similar to the yeast claimed.. See also the rejections under 35 U.S.C § 102, *infra*.

Therefore, it is the Examiner's position that no inventive concept is shared among groups I and II inasmuch as the process of Group II is not specially adapted or required to obtain the products as claimed and a technical relationship is lacking among the claimed inventions involving one or more special technical features because microorganisms are known that **can** possess the required amount of γ -glutamylcysteine and glutathione. See, e.g., Ohtake *et al.* or Sugiyama *et al.*.

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Clearly different searches and issues are involved with each group.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Art Unit: 1651

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in reciting conditional phrases such as "can" and "when" which fail to state positive limitations in the claims. The properties of the strain whenever a different medium is used cannot be determined. It is also noted that the medium to be used is not claim designated. If the strain claimed is intended to be glutathione synthetase deficient, the claim should be amended accordingly.

"Slower growth" is an indefinite uses of a word of degree to modify a limitation. When a word of degree is used to modify a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the limitation as modified by the word of degree, since the medium is not identified with any specificity. Therefore, one of ordinary skill

in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641. Also, it is uncertain now “shows” is determined in this context.

Claim 2 is vague and indefinite, since the limitation “not containing glutathione...” is at least ambiguous. It is uncertain whether applicants intend the simultaneous absence of all of the compounds. Inasmuch as the strain produces at least some of these compounds, it is uncertain how their absence can be assured. Also, in complex media, some of these compounds may be present. The nature of the medium intended should be defined with more particularity.

Claim 4 is vague, indefinite and confusing in the recitation of “wherein glutathione synthetase encoded by a glutathione synthetase gene on a chromosome has deletion of a C-terminus region from an arginine residue at a position of 370”. It is unclear what is intended in this context, since each gene would reasonably be expected to have only one C terminus. Also the recitation of “at a position of 370” renders the claim confusing, since the nucleotide sequence(s) having this deletion is/are not identified with any specificity and there is no clear point of reference as to the position intended.

With respect to claims 5 and 7-9, the “suitable” medium intended cannot be readily determined. Moreover, it is uncertain what is intended by “and utilizing the obtained cells”. These claims are product claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ohtake *et al.*.

The claims are directed to a *S. cerevisiae* strain that can contain 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione during its logarithmic growth phase.

Ohtake *et al.* disclose an *S. cerevisiae* strain that can contain 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione during its logarithmic growth phase. See, e.g., Table III. An extract of the cells was prepared to measure intracellular contents. See, e.g. page 3147, first paragraph.

Claim 4 is included to the extent that the mutant disclosed is glutathione biosynthesis deficient. See also the rejection under 35 U.S.C § 112, *supra*.

Claims 1-3, 5 and 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Sugiyama *et al.*.

The claims are directed to a *S. cerevisiae* strain that can contain 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione during its logarithmic growth phase.

Sugiyama *et al.* disclose an *S. cerevisiae* strain that can contain 1% or more glutamylcysteine and which contains 0.004%-0.1% by weight of glutathione during its logarithmic growth phase. See, e.g., Figure III. An extract of the cells was prepared to measure intracellular contents. See, e.g. page 15536, col. 1.

The method of preparation of the yeast extract of claim 9 does not patentably distinguish the product produced.

Claims 5 and 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuroda *et al.* (JP04066069).

The claims are drawn to a yeast extract composition which has been obtained by a certain process and which contains glutathione.

The cited reference discloses a yeast extract composition which contains glutathione which appears to be identical to the presently claimed yeast composition (see, e.g., Abstract) since it similarly was extracted from *S. cerevisiae* and contains the required compounds. The

referenced yeast composition appears to be identical to the presently claimed yeast composition and is considered to anticipate the claimed yeast composition since it contains the same ingredients. Consequently, the claimed yeast composition appears to be anticipated by the reference.

In the alternative, even if the claimed yeast composition is not identical to the referenced yeast composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced yeast composition is likely to possess the same characteristics of the claimed yeast composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed yeast composition would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

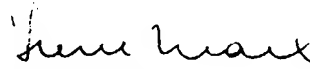
Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.


Irene Marx
Primary Examiner
Art Unit 1651